



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4272]

Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon: Guidance for Industry." We developed the draft guidance to assist food manufacturers that wish to voluntarily label their food product or ingredients (for humans or animals) derived from Atlantic salmon as either containing or not containing products from genetically engineered (GE) Atlantic salmon.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-4272 for "Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist the office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Regarding human food issues: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371. Regarding animal food issues: Kathleen Jones, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-7077.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding

on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

On November 19, 2015, FDA approved a new animal drug application (NADA) related to AquAdvantage Salmon, a GE Atlantic salmon. This is FDA's first approval of an NADA in support of a GE animal for use as food. According to information in the NADA, AquAdvantage Salmon is genetically engineered to reach market size in a shorter period than non-GE farm-raised Atlantic salmon. FDA's Center for Veterinary Medicine reviewed the NADA and made a determination concerning the safety and effectiveness of the new animal drug in AquAdvantage Salmon.

In terms of labeling of food derived from AquAdvantage Salmon, the law requires, among other things, that the label includes a name that accurately describes the basic nature of a food and any other information that is considered material with regard to consequences that may result from the use of the food. In a 1992 policy on foods derived from new plant varieties and a 2001 draft guidance on voluntary labeling of food from GE plants, we explained that: Name changes are appropriate when a food from a GE plant is materially different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food; or when there are other material differences that affect the food's nutritional or functional characteristics.¹ (Elsewhere in this issue of the Federal Register, we are announcing the availability of a final guidance entitled "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.") Changes to the name of the product or other additional labeling are not required if the resulting food is not materially different from its non-genetically engineered counterpart.

¹ See 57 FR 22984, May 29, 1992.

In the process of deciding whether or not to require additional labeling of AquAdvantage Salmon, FDA considered whether food from AquAdvantage Salmon is materially different from non-GE, farm-raised Atlantic salmon. As part of our evaluation, we assessed data and information submitted in response to our August 26, 2010, Federal Register document entitled "Food Labeling; Labeling of Food Made From AquAdvantage Salmon; Public Hearing; Request for Comments" (75 FR 52602), as well as data and information submitted by the sponsor.

Based on our review of the sponsor's data and information, and other information available to the Agency (e.g., FDA's laboratory analyses establishing that AquAdvantage Salmon meets the criteria for Atlantic salmon established for the Regulatory Fish Encyclopedia), we found that the composition, nutritional profile, and safety of food from AquAdvantage Salmon do not differ from food from non-GE, farm-raised Atlantic salmon in any material way, and thus it is as safe and nutritious as food from non-GE, farm-raised Atlantic salmon. For these reasons, we concluded that there is no basis to require additional labeling of food derived from AquAdvantage Salmon.^{2, 3}

II. Guidance on Voluntary Labeling

Recognizing that some consumers are interested in whether a food contains GE Atlantic salmon and some manufacturers may want to respond to this consumer interest, we developed this draft guidance to assist food manufacturers that wish to voluntarily label their food product or ingredients (for humans or animals) as either containing or not containing products from GE Atlantic salmon. FDA's main concern within the context of this guidance is that any voluntary labeling be truthful and not misleading.

² We note that, if a different GE salmon is developed in the future, we will separately assess the data and information about that salmon to determine whether it differs materially from non-GE salmon and, as such, whether additional labeling would be required on food derived from that salmon.

³ Memorandum to File: Office of Nutrition, Labeling and Dietary Supplements, CFSAN: Evaluation of data and information and recommendations related to the labeling of food from AquAdvantage Salmon.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the Federal Register soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a future issue of the Federal Register.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-29904 Filed: 11/23/2015 8:45 am; Publication Date: 11/24/2015]